

REMARKS

Office Action

Rejection under 35 USC 102(b).

Claims 12, 13, 15-16, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Walder-Utz et al. (5,779,720) or Archibald (4,267,842). Applicant respectfully traverses this rejection of the claims for the following reasons. Reconsideration is respectfully requested.

To anticipate a claim under 35 U.S.C. 102(b), a single reference must contain all of the elements of the rejected claim. If a cited reference does not disclose each element of a claim, the reference does not render the claim unpatentable.

Walder-Utz ('720) purports to disclose a substantially C shaped surgical clip. Said clip appears to be used as a clamp to hold together edges of surgical wounds to promote faster healing and to provide cosmetically better healed wounds. However, Walder-Utz fails to disclose, teach, or suggest a device used in grafting or to protect tissue that is being grafted.

Archibald ('842) apparently relates to an arterial sleeve grip device. This is used to join together separated arteries, lumen, or the like. However, Archibald fails to disclose, teach, or suggest a device that is used in grafting or used to protect tissue that is being grafted.

The present invention as defined in the claims and rejected under 35 U.S.C. 102(b) clearly states that the device as described is for assisting in grafting by providing a protective surface to protect the tissue portion of the graft during the surgical operation to attach the graft to a bone.

Clearly the device of the present invention is not described in the cited references. A device, such as a "staple" described in the cited references cannot be used to protect tissue from

the effects of an interference screw in a grafting procedure. The devices of the prior art do not have a "protective exterior surface".

Hence, it is applicant's position that the no single cited reference contains each and every limitation of the claimed invention. Applicant urges the Office to reconsider this rejection and
5 accordingly withdraw the rejection.

Rejection of Claim 19 Under 35 U.S.C. 103(a).

Claim 19 stands rejected under 35 U.S.C. 103 (a) as being unpatentable over Archibald or Walder-Utz et al. as applied to claim 12 under the rejection under 35 U.S.C. 102(b) (above), and
10 further in view of Shichman et al. (5439479). It is Examiner's position in this rejection that although Walder-Utz et al. is not specific to the material composition of the surgical clip, Shichman et al. teaches that a bioabsorbable material may be used to make surgical clips.

Applicant respectfully requests that Archibald be removed as a cited reference in this rejection under 35 U.S.C. 103 since this reference clearly teaches away from the use of a
15 bioabsorbable material in the construction of the device of that reference. At Column 2, lines 20-24, Archibald states that it is desirable that the sleeve grip 21 (reference number not shown in figure) is formed from the same material as the inner tube 1 and etched Teflon has been found to be a suitable substance, since it has a very low likelihood of rejection by the body. Teflon is known to be a relatively biological inert material. This is completely opposite to a
20 "bioabsorbable material" where the substance will not persist but decompose overtime and be absorbed into the body system.

Claim 19 of the present invention describes the grafting device of Claim 12 being made of bioabsorbable material.

Both Walder-Utz et al. and Shichman et al. appear to relate to improved surgical clips for closing incisions in body tissue. Shichman et al. appears to teach the use of bioabsorbable material for the composition of the surgical clips. However, there is no teaching or suggestion that would lead one skilled in the art to combine this teaching with Walder-Utz et al. to arrive at
5 the instant rejected Claim 19 (dependent on Claim 12) of the present invention.

There is no teaching or suggestion in Walder-Utz et al. or Shichman et al. that would lead one skilled in the art to the use the respective devices in a grafting or surgical reconstructive procedure. Hence there is no teaching or suggestion that the use of the bioabsorbable material of Shichman would be applicable or useful in a protective exterior surface device in view of the
10 cited prior art taken alone or in any combination. Therefore, the Office has failed to establish a *prima facie* case of obviousness.

Rejection of Claim 14 Under 35 U.S.C. 103(a).

Claim 14 stands rejected under 35 U.S.C. 103 (a) as being unpatentable over Walder-Utz
15 et al. or Archibald as applied to claim 12 under the rejection under 35 U.S.C. 102(b) (above), and further in view of Medinaceli. It is noted that the Office has cited three U.S. Patents in the name of Medinaceli, but did not indicate which one or if all of the patents are relied upon in this rejection.

It appears that Medinaceli I (4,586,504) and Medinaceli III (5,122,151) both make some
20 reference to “inscribed measuring lines and guide points” and “inscribed guide lines” respectively. In the first instance (‘504) these lines and points enable the diameter of the nerve or other structure being reconnected, as well as providing stump lengths to be secured and trimmed to achieve optimum results. Similarly, (‘151) relates to inscribed guidelines on the

connector to indicate proper placement of the nerve stumps for optimum healing. Medinaceli II (4,306,561) relates to a holding apparatus for repairing severed nerves.

Whereas Claim 14 is dependent on Claim 12, which describes the present invention, is not taught or suggested by any of the cited references the rejection based on such teachings are not valid. None of the references teach an exterior protective surface necessary for the grafting procedure to protect the grafting tissue, as from an interference screw.

The Office has combined the device of either Walder-Utz or Archibald with the teachings of visual markings or indicators taught by any of de Medinaceli. On the issue of obviousness, the combined teachings of the prior art as a whole must be considered. Clearly, it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art to which it pertains.

In determining obviousness, section 103 expressly requires considering the claimed invention “as a whole”. Focusing on the section 103 inquiry or a particular aspect of the invention that differs from the prior art, improperly disregards the “as a whole” statutory mandate.

The objective evidence of nonobviousness is extremely important; the Office cannot disregard this evidence. The factual evidence derives from the analysis mandated by *Graham v. John Deere Co.* 148 U.S.P.Q. 459 (1966). (1) The scope and content of the prior art; (2) the differences between the prior art and the claimed subject matter, and (3) the level of ordinary skill in the art at the time the invention was made. It is urged the Office did not establish a *prima facie* case of obviousness in this instance.

The prior art relied upon coupled with the knowledge generally available in the art at the time of the invention must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. The prior art reference or combination, as in this case, must teach or suggest all the limitations of the rejected claim. The teachings and suggestions, as well as the expectations of success, must come from the prior art, not the applicant's disclosure.

The Office apparently did not consider the prior art references and their relationship and teachings in their entirety. Whereas, de Medinaceli I and III teach inscribed guide lines on a connector for repair of severed nerve fibers, the guide lines are placed there to indicate proper length and placement of nerve stumps in a nerve connector (retainer) to obtain optimum healing of the repaired severed nerves. This is necessary to insure proper placement of the nerve stumps. The lines and pattern of de Medinceli I indicate the nerve diameter, the general position of the nerve on the device, and the distance at which the fixation stitches must be placed from the tip of each stump and the amount of tissue that must be trimmed from the stumps.


In rebuttal to the rejection under 103, applicant respectfully submits the marking or indicators to facilitate proper placement of the device *in vivo* would not have been obvious to one skilled in the art in view of the cited prior art, when the objective evidence is analyzed. In the present invention the guide mark is provided to provide a visual reference to assist in the insertion of an interference screw into a bone tunnel to secure within the tunnel wall a bone block, for example, a bone-tendon-bone ligament graft. Without the graft device 100 having a protective surface, the interference screw could damage the tissue portion of the graft. It required in this procedure for the screw be positioned and aligned parallel to the axis of the bone tunnel.

In the de Medincoli instances the guidelines are used as markings to indicate the nerve diameter, the general position of the nerve on the device; and the distance at which the fixation stitches must be placed from the tip of each stump and the amount of tissue that must be trimmed from the stumps. This is in contrast to the instant invention, which uses the guidelines as
5 markings on a protective shield to assist in aligning the axis of the interference screw to be parallel to the axis of the bone tunnel.

CONCLUSION

For all of the above reasons, the applicant submits that the present application is in
10 condition for allowance. If the examiner has any questions regarding the application or this response, the examiner is encouraged to call the applicant's attorney, Ian Burns, at (775) 826-6160.

15 Respectfully submitted,

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